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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,832	07/01/2003	Harald Stein	086035-000000US	3864

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EXAMINER	
YAO, LEI	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 11/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/612,832	STEIN ET AL.	
	Examiner	Art Unit	
	Lei Yao, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 6-30* is/are pending in the application.

4a) Of the above claim(s) *8,10,12-14,19-28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,6,7,9,11,15-18,29 and 30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/20/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *PTOL90*.

REQUEST FOR CONTINUED EXAMINATION

The request filed on 3/20/06 for a Continued Examination (RCE) under 37 CFR 1.114 based on Application No. 10612832 is acceptable, and a RCE has been established. An action on the RCE follows. Applicant's election with traverse of Group I (claims 1, 6-18, 29, and 30) with species enzyme in the reply to election/restrictions for the amendment in RCE filed on 8/25/06 is acknowledged.

Applicants argue that two reagent inventions (group I and II) can be examined together without serious burden. In response to this argument, although both group I and II are drawn to reagents (antibody in group I and T-cell receptor fragment in group II), which share the common feature of binding to two spatially separated positions on CD30, two reagents are patentably distinct product since they do not share common structures and functions. As discussed in the election/restriction they fails Harnish test. In re Harnish, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and Ex parte Hozumi, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Because they are distinct in structure, function and utilities, searching the inventions of Group I and Group II are not coextensive and would impose a serious search burden. Thus, the requirement is still deemed proper and is therefore made **FINAL**.

Claims 2-5 have been cancelled. Claims 1 and 6-30 are pending. Claims 8, 10, 12-14, and 19-28 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention or species. Claims 1, 6, 7, 9,11,15-18, 29, and 30 to the extent of enzyme are examined on the merit.

Previous final Office Action dated 8/12/05

The rejections in the previous Office action, dated 12/19/05, including rejection of claims under 35 U.S.C. 112 first paragraph and rejection of claims under 35 U.S.C. 102 and 103 are withdrawn. **If any rejection/objection is maintained, it will be stated again below.**

Information Disclosure Statement

The information disclosure statement (s) (IDS) submitted on 3/20/06 are/is considered by the examiner and initialed copies/copy of the PTO-1449 are/is enclosed.

Claim Objections

1. The claim 9 is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: Claim 9 is dependent on claim 8, which is drawn to a non-elected invention (toxin). Morever, claim 8 is only drawn to a toxin, claim 9 is drawn to toxic proteins, enzymes, or proenzymes, claim 9 does not further limit the claim 8. For the purpose of examination, claim 9 is treated as further drawn to claim 1.

2. The claim 1 is objected to as being drawn to a nonelected invention. Applicant has elected group 1, drawn to antibody and antibody fragments in claim 1 for examination at this time. The claim contains subject matters drawn to non-elected invention. Claim 1 is required to re-write as a base claim for the purpose of examining the reagent, kit, or composition comprising antibody or antibody fragment.

3. Claims 15-18 are objected to for typographical error as " isolated cell". Amending the claim to "an isolated cell" would obviate this objective. Appropriate correction is required.

4. Claim 1, 6, 7, 9, and 11 are to for typographical error as "reagent". Amending the claim to " a reagent" in claim 1 and "the reagent" in 6, 7, 9, and 11 would obviate this objective. Appropriate correction is required.

Sequence Requirements

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). This application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825. Specifically, **SEQ ID No(s) is required for the sequences in specification on pages 12 and 15 and amended specification on page 16.** If these sequences are found in the sequence listing filed 10/15/2003, Applicants need only insert the appropriate SEQ ID Nos. However, if these sequences are not part of the listing filed 6/18/04, then applicants need to comply with the sequence rules. Applicant is reminded to check the entire disclosure to ensure that the application is in sequence compliance comprising inserting "SEQ ID NO: 13" after "CEPDY".

Any questions regarding compliance with the sequence rules requirements specifically should be directed to the departments listed at the bottom of the Notice to Comply (see attached form, PTO L90).

Claim Rejections - 35 USC § 112

The following is a quotation of the **second paragraph** of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 6, 7, 9, 11, 15-18 and 29-30 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. Claims 1, 6, 7, 9, 11, 15-18 and 29-30 are indefinite because the term "the reagent enters into interactions with at least two spatially separated position on CD30" in claim 1 is not clear. It is not clear whether "enters into interaction with...." means "bind to...."or has other meanings. The specification does not provide a definition or further explanation for the claims. Therefore, the metes and bounds of the claims cannot be determined. Furthermore, claim 1 also renders the dependent claims indefinite. For the purpose of examination, term "enters into interaction with" is interpreted as "binds to" in the following rejections.

The following is a quotation of the **first paragraph** of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 6, 7, 9, 11, 15-18 and 29-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims are drawn to a reagent characterized in (interpreted as comprising in this rejection) the antibodies binding to (enters into interaction with) at least two separated positions with core sequence CEPDY (SEQ ID NO: 13) of CD30. Claims are also drawn to an isolated cell producing the reagent or antibody above and show essential feature of the cell as DSM ACC2548. Thus, the claims are inclusive of a genus of reagents or antibodies, which bind to two separated amino acid sequences, each has a core sequence CEPDY of CD30 and inclusive of a genus of cells having essential feature of the cells and producing antibodies having such binding abilities.

The specification discloses that the reagent of the invention is suitable for use in tumor-diagnosis and therapy of inflammatory diseases (page 4). The specification also discloses that the reagent covers one antigen domain as occurs with antibodies and antibody fragments (page 5). The specification further discloses the reagent is antibody, TCR, DNA, or RNA (page 5). However, the written description in this case only set forth one monoclonal antibody secreted by a cell DSZ1 stored at the DSM under the number DSM ACC2548, which specifically binds to sequence of "DCRKQ**CEPDY**YLD and GDCRKQ**CEPDY**YL" of CD30 by epitope mapping and **CEPDY** as a core sequence (page 15, paragraph 2 and figure 3). The claims encompass reagents or antibodies having significant structural and functional dissimilarity and diversity as compared to this particular antibody made from DSM ACC2548. The monoclonal antibody (DSM ACC2548) does not anticipate the claimed genus because the genus includes reagents or antibodies, which differ widely in structural attributes from the antibody secreted by DSM ACC2548. Thus, one skill in the art cannot envision the detailed chemical structure of the encompassed "reagent" or antibodies.

A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or by describing structural features common the genus that "constitute a substantial portion of the genus." See University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997): "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNA, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." The Federal Circuit has recently

clarified that a DNA molecule can be adequately described without disclosing its complete structure. See Enzo Biochem, Inc. V. Gen-Probe Inc., 296 F.3d 1316, 63 USPQ2d 1609 (Fed. Cir. 2002). The Enzo court adopted the standard that the written description requirement can be met by "show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristic, i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. " Id. At 1324, 63 USPQ2d at 1613".

The court has since clarified that this standard applies to compounds other than cDNAs. See University of Rochester v. G.D. Searle & Co., Inc., F.3d ,2004 WL 260813, at *9 (Fed.Cir.Feb. 13, 2004). The specification neither provides a representative number of reagents or antibodies that encompass the genus that is characterized by binding to two spatially separated positions having a core amino acid sequence of **CEPDY in CD30,** nor does it provide a description of structural features that are common to the reagent or antibody except binding to CEPDY in CD30. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variants, the disclosure of the monoclonal antibody secreted by DSM ACC2548 to an epitope having a core sequence **CEPDY** of CD30 is insufficient to describe the genus. Thus, one of skill in the art would reasonably conclude that the inventor(s), at the time the application was filed, did not have possession of the claimed invention.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure(s) and functional attribute(s) of the encompassed genus of claimed reagents or antibodies, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and

reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only the antibody secreted by DSM ACC2548 and a cell having number DSM ACC2548, but not the full breadth of the claims, meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

The response to the final office action argues that applicants have provided the structural attribute of the core sequence of the epitopes of the CD30 antigen to which the reagents bind. In response to this argument, current claims are drawn a reagent comprising any antibody binding to the core sequence of CD30 or a cell making such antibody. Applicants have not provided a representative number of claimed reagents or antibodies. Applicants have not limited the claims to specific antibody made by a cell, DSM ACC2548. Thus, the rejection is made again as above.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 1, 6, 15-17, and 29-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Lemke et al., (US Patent NO: 6033876, Mar, 2000, provide in previous office action).

The set of claims is drawn to a reagent comprising an antibody binding to two separated amino acid sequence having core sequence CEPDY in CD30, wherein the antibodies are chimerized antibody, antibody fragments, or humanized antibody. Claims are drawn to an isolated cell to produce antibody or show essential feature of the cells as a cell deposited in DSM. The claims are also drawn to a pharmaceutical composition and a kit containing the reagent or the antibody.

Lemke et al., disclose anti-CD30 antibodies binding to CD30 antigen, which are used for diagnosing or treating a disease. Lemke et al., disclose that the antibodies can be used as whole monoclonal antibodies, chimeric, humanized antibody, and antibody fragments (FV, (FV)2, Fab, Fab', or F(ab)2) (col 4, line 52-60). Lemke et al., disclose isolated cells producing the antibodies and cells containing a recombinant DNA encoding part of antibodies (col 7). Lemke et al., also disclose a pharmaceutical composition comprising the antibodies to CD30 (section 6, line 20-30), which is used for inhibiting release of sCD30 (col 2 and col 9-10).

Although Lemke et al., do not explicitly teach a kit containing the antibody for diagnosing or treating CD30 related disease, claim 30 is anticipated by Lemke et al., because Lemke et al., disclose diagnosis of a disease with the antibodies to CD30, because formation of a kit using known component is within the purviews of one skilled in the art and because claim 30 recites a kit comprising antibody to CD30 for diagnosing a disease and a instruction of using the reagent. See MPEP 2112.01-III as following:

> Where the only difference between a prior art product and a claimed product is printed matter that is not functionally related to the product, the content of the printed matter will not distinguish the claimed product from the prior art. In re Ngai, ___ F.3d ___, 2004 WL 1068957 (Fed. Cir. May 13, 2004.

The antibodies to CD30 disclosed by Lemke et al., appear to meet the requirements of the instant claims regarding binding to the epitope of CD30. The Office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the

absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art and to establish patentable differences. See In re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

The response to the final office action argues *that the antibody disclosed by Lemke et al., binds to dominant binding region within CRD2 and 5 of CD30, which is different form the CEPDY epitope.* In response to this argument, it is not clear whether CRD2 and 5 contain the binding domain sequence including an amino acid sequence **CEPDY**. The claims are drawn to an antibody binding to two separated positions comprising CEPDY, which may not specifically bind to the amino acids CEPDY in the binding domain. Thus, the antibodies binding to any epitope having a core sequence CEPDY in the CD30 would anticipate claimed antibody.

2. Claims 1, 6, 15-17, and 29-30 are rejected under 35 U.S.C. 102(e) as being anticipated Mohler et al., (US Patent Application Publication NO: 20020064527, effective filing date, Aug, 2001, provide in previous office action).

The claims are set forth above.

Mohler et al., disclose polyclonal antibodies, which bind to CD30 antigenic polypeptides (para 50-60). Mohler et al., also disclose that the antibodies are chimeric or fragment of the antibodies to CD30 and a cell containing a DNA encoding the antigen binding peptide (para 59-60). Mohler et al., further disclose that forming a pharmaceutical composition with the antibodies for the purpose of treating a disease (para 11).

Although Mohler et al., do not explicitly teach a kit containing the antibody for diagnosing or treating CD30 related disease, claim 30 is anticipated by the antibodies because Mohler et al., disclose screening a disease with the antibodies to CD30, because formation of a kit using known component is within the purviews of one skilled in the art and because claim 30 recites a kit comprising antibody to CD30 for diagnosing a disease and a instruction of using the reagent. See MPEP 2112.01-III as following:

> Where the only difference between a prior art product and a claimed product is printed

> matter that is not functionally related to the product, the content of the printed matter will not distinguish the claimed product from the prior art. In re Ngai, ___ F.3d ___, 2004 WL 1068957 (Fed. Cir. May 13, 2004.

It would be reasonable to conclude that the polyclonal antibodies to antigenic peptides of CD30 include the antibodies binding to polypeptide having a core sequence CEPDY of CD30. The Office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art and to establish patentable differences. See In re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 9 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lemke et al., or Mohler et al., applied in the claim 1 above and further in view of Deonarain et al., (Br J Cancer, vol 70 page 786-94, 1994, provide in previous office action).

Claims 9 and 11 are further drawn to claim 1, wherein the reagent is linked with enzymes from the group of the phosphodiesterases.

Lemke et al., and Mohler et al., teach that anti-CD30 antibodies.

Lemke et al., and Mohler et al., do not teach that the anti-CD30 antibodies are linked to an enzymes or phosphodiesterases.

Deonarain et al., teach ribonuclease (RNas), an enzyme from group of phosphodiesterases, and using the enzyme for cancer therapy. Deonarain et al., also teach that RNase is fused to an antibody or an antibody fragment. Deonarain et al., further teach that the fusion protein is cytotoxic to the cells at low concentrations (page 792, column 1, paragraph 1).

It would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the teaching of Lemke et al., or Mohler et al., on anti-CD30 antibodies with the teaching of Deonarain et al., on fusing an antibody with RNase in order to benefit both functions of the antibodies and the enzymes. One of ordinary skill in the art would have been motivated to link the CD30 antibodies with RNase according to the teachings of Lemke et al., or Mohler et al., and Deonarain et al., in order to take the advantage of cytotoxic function of the enzyme for the tumor treatment with antibody to CD30. One of ordinary skill in the art would have been motivated with a reasonable expectation of success to make such antibody conjugate because Lemke et al., and Mohler et al., and have shown that an antibody binds to CD30 antigen and used the antibody for diagnosing or treating a disease and Denarain et al., have shown a method of making such antibody conjugate and shown that a antibody fused with RNase is cytotoxic to cells.

Conclusion

No claims are allowed. The isolated cell and antibody produced by the cell deposited at DSM having number DSMACC2548 in claim 7 and 18 are free of art. However, both Mohler et al., and Lemke et al., disclose antibodies, which appear to have same function as discussed above. Neither Mohler et al.,nor Lemke et al., teach or suggest the antibody produced by a cell, DSMACC2548.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lei Yao, Ph.D. whose telephone number is 571-272-3112. The examiner can normally be reached on 8am-6.00pm Monday-Thursday.

Any inquiry of a general nature, matching or file papers or relating to the status of this application or proceeding should be directed to Kim Downing for Art Unit 1642 whose telephone number is 571-272-0521

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lei Yao, Ph.D.
Examiner
Art Unit 1642

LY

JEFFREY SIEW
SUPERVISORY PATENT EXAMINER

Notice to Comply	Application No. 10612832	Applicant(s) Stein et al	
	Examiner Lei Yao	Art Unit 1642	

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☐ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☒ 7. Other: need SEQ ID numbers for sequences listed on page 15, 16 etc.

Applicant Must Provide:

☐ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

☒ An initial or substitute paper copy of the "Sequence Listing", **as well as an amendment specifically directing its entry into the application**.

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216 or (703) 308-2923
For CRF Submission Help, call (703) 308-4212 or 308-2923
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